



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,456	01/09/2004	Kary B. Mullis	13139-0104 (13721.105006)	7994
20786	7590	06/22/2009	EXAMINER	
KING & SPALDING 1180 PEACHTREE STREET, NE ATLANTA, GA 30309-3521			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	
			MAIL DATE	DELIVERY MODE
			06/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/754,456	Applicant(s) MULLIS, KARY B.	
	Examiner David A. Saunders	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7,13-18,22-32 and 34-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,7,13-18,22-29,31,32 and 35-42 is/are rejected.
- 7) ☒ Claim(s) 2,3,34 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/15/08</u> . | 6) <input type="checkbox"/> Other: _____ |

AMENDMENT ENTRY

Amendment of 4/1/09 has been entered. Claims 1-4, 7, 13-18, 22-32 and 34-42 are pending.

Since all bases of rejection, but for the double-patenting rejection, have been overcome, claims 1-4, 7, 13-18 and 22-31 of Group I have been rejoined.

Claims 1-4, 7, 13-18, 22-32 and 34-42 are under examination.

CORRECTIONS REGARDING PREVIOUS OFFICE ACTION

The following corrections pertain to the previous Office action:

The para. spanning page(s) 4-5 was unintended, since this application does not have joint inventors.

OBJECTION(S)/REJECTION(S) OF RECORD WITHDRAWN

The amendment has overcome previously stated issues as follows:

The rejection of claim(s) 34 and 38-39 under 35 USC 112, 2nd paragraph.

The rejection of claim(s) 37 under 35 USC 112, 1st paragraph, since page 33 has incorporated by reference "All publications and patents mentioned herein".

The 102(b)/103 prior art rejection of claim(s) 32, 35, 37, 39 and 41-42 based upon Mullis WO 01/45734. Applicant has amended claim 32 to recite that "the pre-existing immune response component is a B-cell/humoral or a T-cell/cellular immune response component." Claim 32 thus does not extend in scope beyond what was disclosed in the intervening WO 01/45734 publication, filed as International Application PCT/US00/35179. Instant claim 32 is thus given benefit of the filing date of International Application PCT/US00/35179.

MODIFIED DOUBLE PATENTING REJECTION

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 7, 13-18, 22-29, 31-32, and 35-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 7-9, 11, 19-21, 24-25, 28 and 30-38 of copending Application No. 11/606,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to immunity linker molecules that have both first and second binding sites which are aptamers. The copending claims are broader in terms of the nature of the first site; however, the copending claims clearly encompass the case in which both the first and second binding sites are aptamers (e.g. copending claims 2 and 19, which recite that the immunity linker molecule comprises “a nucleic acid”, which would in turn encompass an aptamer).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Instantly, the double patenting rejection has been modified by the addition of rejoined claims of Group I to the stated rejection. Also the rejection has been modified by the addition of more claims of Group II to the stated rejection; this is because the examiner has presently relied upon the features of dependent claims of the copending application, irrespective of whether these features are taught in composition or in method claims. The examiner can rely upon the teachings of copending composition or method claims, in order to reject the instant method or composition claims, respectively, because the composition and method claims are properly considered as not patentably distinct following rejoinder.

Applicant's response of 4/1/09 has not provided a disclaimer. While a disclaimer has been filed and approved in copending application 11/606,564, it is impossible to determine whether the instant or the copending application might issue first. A disclaimer is therefore required in the instant application.

NEW OBJECTION(S) TO CLAIMS

Claim 1 is objected to because of the following informalities: Lines 5-8 of claim 1 constitute one para. which starts with a description of "the first binding site" and ends with a reference to the "second binding site". At line 7 "wherein the immunity" should start a new para.

In claim 1, line 7, "and" is surplusage since "and" is recited at the end of line 9.

Claim 32 is objected to because of the following informalities: In claim 32, 3rd line from the end, both a period and a comma appear after "target".

Claim 32 is also clumsy because it provides a "wherein" clause that describes the "pre-existing immune response component" starting 3 lines below the point at which the claim previously describes the nature of the "pre-existing immune response component". The "wherein" clause that describes the "pre-existing immune response component" should be moved up to the 5th line.

Appropriate correction is required of all of the above claims.

REJECTION(S) UNDER 35 USC 112, SECOND PARAGRAPH

Claims 23 and 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 23, "the pre-existing immunity" lacks antecedent basis. Since claim 1 has, instead, referred to a "pre-existing immune response component".

In claim 25, line 2 it is not clear if "more than one binding site" refers to the "first" or the "second" binding site of claim 1. It is believed that the "second" is intended.

In claim 26, line 1 it is not clear if "the binding sites" refer to the "first", the "second", or both binding site(s) of claim 1. It is believed that the "second" is intended.

ART OF INTEREST

The prior art made of record in the IDS of 12/15/09 and not relied upon is considered pertinent to applicant's disclosure. The Gold et al reference (5,475,096) was cited as prior art against the claims in copending application 11/606,564. The Gold et al reference is not cited against the instant Claims because the reference is not relevant to claims which require that both the first and the second binding sites be aptamers.

The prior art made of record by the examiner and not relied upon is considered pertinent to applicant's disclosure. Leung et al (6,090,381, cited on PTO-892) show an immunity linker molecule with 1) a first binding site which is an alpha-gal epitope and 2) a second binding site which is an anti-tumor antigen antibody. Leung et al provide no teachings that either the first or second site may be an aptamer.

FINALITY

Applicant's amendment, that necessitated rejoinder of claims 1-4, 7, 13-18 and 22-31 of Group I, has necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays. The examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax number where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 6/15/09 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644